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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,522

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Edward J. Seppi

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EXAMINER

KISH, JAMES M

ART UNIT

PAPER NUMBER

3737

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/687,522	Applicant(s) SEPPI ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47, 56-67, 69, 71 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47, 56-67, 69, 71 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2009 has been entered.

Response to Arguments

Applicant's arguments filed April 8, 2009 have been fully considered but they are not persuasive.

The Applicant argues on the bottom of page 12 that the combination of Ogawa and Hughes, and then the combination of Ogawa and Acharya at the bottom of page 13 are both improper. The arguments in the Advisory Action are commented on as being insufficient to provide motivation. The Applicant specifically states that the fact that the references are "capable of being combined" and that because two references allegedly disclose similar elements is not enough to teach obviousness. The Examiner does not disagree. However, the Applicant fails to respond to the further motivation supplied by the Examiner. That is, "the combination of Hughes's use of contrast agent imaging with the use of 3D imaging as taught by Ogawa would at least allow a doctor to view the vessels of interest (or the entire circulatory tree) while also viewing the surrounding soft

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tissue while attempting to diagnose a disease or illness of the vessels.” The combination of Ogawa and Hughes would provide a system not drastically unlike that of Salb (US Patent No. 6,226,352) (from Abstract – “The viewer may interactively control the relative proportion of radiographic density contributed by imaging agent, soft tissue, and bone to the displayed image...). And regarding Ogawa and Acharya, “Ogawa may not explicitly state that there is a need to characterize plaque, however, Ogawa teaches the creation of images of good contrast of soft tissue. Therefore, this would aid in the viewing and analyzing of the soft tissue portion of non-calcified plaque.”

Furthermore, Ogawa teaches “Therefore, a pattern of a diseased part, which is hidden behind a pattern of a specific structure, can be detected appropriately. As a result, diagnosis of an illness can be made efficiently and accurately. However, the “diseased part” is never clearly defined by Ogawa. Both Hughes and Acharya teach methods in which specific diseases are being diagnosed via similar imaging methods (thereby fulfilling the “same field of endeavor” requirement.

Based on any and all of the previously discussed reasons and motivations, the combination of Ogawa with either of Hughes and Acharya is deemed proper.

Regarding the claim amendments and the arguments supporting such amendments, the Examiner respectfully disagrees that Ogawa in combination with Hughes fails to teach “creating a contrast-enhanced volumetric composite image, nor a portion of a contrast-enhanced volumetric composite has a feature indicating cancerous tissue (Remarks, page 12).” Ogawa teaches a volumetric image creation, Hughes teaches the use of contrast agents and Hughes considers that it has become

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“increasingly important to visualize abnormalities in the arteries of the heart, the neck, the brain and other vascular beds to detect the presence of dangerous obstructing lesions as well as the blood-flow patterns that develop in the vicinity of malignant tumors (column 1, lines 15-19).” Hughes teaches the imaging of blood vessels and it would be obvious to one of ordinary skill in the art to use these images to visualize abnormalities, such as tumors or other lesions, via these images (which simply relates to the old subject matter of claims 68, 70 and 72, which was previously rejected in view of Ogawa in combination with Hughes). Also, (as previously stated) Ogawa teaches image of a pattern of a diseased part in the object (column 2, lines 1-6) and it would be obvious to one of skill in the art that visualization of patterns such as blood vessels and blood-flow patterns (as explicitly described in Hughes) would relate directly to the “diseased part” stated in this portion of Ogawa. Therefore, Ogawa in combination with Hughes still teaches the claimed subject matter even in view of the amendments.

For the same reason stated above with regard to Ogawa teaching the diseased part, the combination of Ogawa in combination with Acharya teaches the claim amended portion related to “a feature indicating cancerous tissue.” Similarly, Ogawa teaches volumetric imaging and Acharya teaches the use of contrast agents.

Regarding the amendments related to “at least one of storing... and displaying...,” Ogawa teaches “The 3D image or the tomographic image of the object is displayed on the image displaying means **40** (column 7, lines 26-32).”

Based on these previous arguments, the rejections of the claims still stand. However, the 102(b) rejection of Ogawa has been removed and the rejection of claims

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41 and 42 have been changed to incorporate the 103 rejection of Ogawa and Hughes.

This is because, while Ogawa teaches a “diseased part” which would encompass the subject matter of cancerous tissue, it would not necessarily anticipate cancerous tissue, but would make this obvious. Hence, the removal of the 102(b) rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-7, 10-14, 17-33, 36-40, 43-47, 56-59 and 61-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Hughes et al. (US Patent No. 4,432,370). Ogawa discusses the phenomenon of separating structures and

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substances based on having different radiation absorptivity (similar to dichromography), however, Ogawa does not explicitly describe the use of a contrast agent.

In a similar field of endeavor, Hughes teaches producing an x-ray image for a blood vessel by directing synchrotron radiation at first and second selected energy levels through the vessel, detecting the attenuated radiation and logarithmically subtracting the two signals. Also see column 2, lines 36-45, where digitizing the images is described. Other elements such as samarium or europium can be used as contrast agents (column 5, lines 60-64). Also see column 1, line 66 through column 2, line 7. it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a contrast agent into the system and methods of Ogawa in order to create a high fidelity picture of the entire circulatory tree (column 2, lines 9-10 of Hughes).

Regarding claims 62 and 64, see column 8, lines 5-20 (and/or Figure 2) of Ogawa.

Regarding claims 63 and 65, see column 5, lines 47-65 (and/or Figure 1) of Ogawa.

With regard to claims 29, 32-33, 36-37, 40, 43, 45-47 and 66-67, in the situation where the Applicant disagrees with the interpretation that the use of (or lack of) a contrast agent does not alter the set of stored instructions on the computer product, these claims are rejected over Ogawa in view of Hughes because Hughes teaches the use of contrast agents.

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Claims 1, 6-10, 14, 17, 19-21, 29, 32-37, 39-40, 43, 45-47, 56-57 and 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Acharya et al. (US Patent No. 6,922,462).

Ogawa discusses the phenomenon of separating structures and substances based on having different radiation absorptivity (similar to dichromography), however, Ogawa does not explicitly describe the use of a contrast agent.

In a similar field of endeavor to that of Ogawa, Acharya teaches a system and method of plaque characterization. The method comprises obtaining a first and second set of image data at a first and second energy level and calculating a third set of image data by subtracting each second pixel element from the corresponding first pixel element (see Abstract). The method may be performed on several imaging modalities (column 4, lines 6-14). See column 4, lines 60-66 concerning different orientations. Column 6, lines 13-37 describes an embodiment of Acharya of imaging without a contrast agent, much like that of Ogawa. Column 6, lines 18-52 describes a similar procedure, except with the use of a contrast. It would have been obvious to one of ordinary skill in the art to utilize a contrast agent in the methods and systems of Ogawa in order to view and analyze the soft tissue portion of non-calcified plaque (column 6, lines 51-52 of Acharya).

Regarding claims 62 and 64, see column 8, lines 5-20 (and/or Figure 2) of Ogawa.

Regarding claims 63 and 65, see column 5, lines 47-65 (and/or Figure 1) of Ogawa.

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With regard to claims 29, 32-33, 36-37, 40, 43, 45-47 and 66-67, in the situation where the Applicant disagrees with the interpretation that the use of (or lack of) a contrast agent does not alter the set of stored instructions on the computer product, these claims are rejected over Ogawa in view of Acharya because Acharya teaches the use of contrast agents.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa in view of Hughes, as applied to claim 40 above, and further in view of Trauernicht (US Patent No. 5,629,968). Ogawa in combination with Hughes is previously described in the rejection of claim 40. However, there is no discussion of the manner in which the images are initially detected. Trauernicht discloses an apparatus and method for obtaining radiographic images of an object. Figure 3 shows two detectors separated by a beam stop device. The first detector receives the entire radiation dose. The beam stop "deactivates" certain lines of the second detector by not allowing those radiation beams to pass through it. These two images may be combined in registration to provide a composite image of enhanced quality relative to that of the two components (column 5, lines 8-23 and lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a beam stop, as taught in Trauernicht, in the system of Ogawa to prevent certain lines of radiation to proceed to a detector in order to gain a composite image with enhanced quality.

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Claims 3 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Hughes et al., as applied to claims 1 and 14 above, and further in view of Trauernicht. Ogawa in combination with Hughes is previously described. However, there is no discussion of the manner in which the images are initially detected. Trauernicht discloses an apparatus and method for obtaining radiographic images of an object. Figure 3 shows two detectors separated by a beam stop device. The first detector receives the entire radiation dose. The beam stop “deactivates” certain lines of the second detector by not allowing those radiation beams to pass through it. These two images may be combined in registration to provide a composite image of enhanced quality relative to that of the two components (column 5, lines 8-23 and lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a beam stop, as taught in Trauernicht, in the system of Ogawa in view of Hughes to prevent certain lines of radiation to proceed to a detector in order to gain a composite image with enhanced quality.

Claims 69, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa in view of Hughes as applied to claims 1, 22 and 29 above, and further in view of Keyes et al. (US Patent No. 4,482,918) – herein referred to as Keyes. Ogawa in combination with Hughes teaches all of the claimed subject matter except for the time-resolved kinetics of the contrast agent. Fig. 3 of Keyes illustrates a plot of how concentration of an x-ray contrast medium in a blood vessel would vary with time. Based on this information the imaging would be sequenced around the concentration to

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acquire specific contrast exposures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Keyes in the methods and systems of Ogawa and Hughes in order to determine the concentration of iodine in the vessels of interest at key moments in order to acquire the best possible images for the diagnosis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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